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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,520	01/21/2004	David I. Freed	06530.0309	1095

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EXAMINER

KASZTEJNA, MATTHEW JOHN

ART UNIT PAPER NUMBER

3739

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/760,520	FREED, DAVID I.	
	Examiner	Art Unit	
	Matthew J Kasztejna	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 8, 28, 47-50, 54 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,162,209 to Gobron et al.

In regards to claims 1, 28, 47-50, 54 and 58, Gobron et al. disclose a medical device comprising: a proximal handle 140; a distal assembly for performing a medical procedure; an elongated member 110 having a lumen and connecting the proximal handle to the distal assembly, where actuation of the proximal handle causes the distal assembly to perform a medical procedure; an end effector 150 and a distal member 160 defining a flow path therein for fluid communication between the lumen and on outside of the elongated member (see Col 5, Lines 7-31 and Fig. 2). The apparatus of Gobron et al. is inherently capable of performing the recited method steps.

In regards to claim 3, Gobron et al. disclose a medical device including a port 132 which is in fluid communication with the lumen (see Col 5, Lines 10-13).

In regards to claim 8, Gobron et al. disclose a medical device wherein the end effector includes a snare loop 152 (see Fig. 4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 2, 14-15, 34-36, 38-40, and 43-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,162,209 to Gobron et al. in view of U.S. Patent No. 6,589,252 to McGuckin, Jr.

In regards to claims 2, 14-15, 34-36, 38-40 and 43-46, Gobron et al. disclose a medical device comprising: a proximal handle 140; a distal assembly for performing a medical procedure; an elongated member 110 having a lumen and connecting the proximal handle to the distal assembly, where actuation of the proximal handle causes the distal assembly to perform a medical procedure; an end effector snare loop 150 and a distal member 160 defining a flow path therein for fluid communication between the lumen and on outside of the elongated member but is silent with respect to the flow path defined by the distal member having a cross-sectional flow area less than the cross-sectional flow area of the lumen and lacks a connector for receiving cautery current. McGuckin, Jr. teaches of an analogous device wherein shaft 20 includes an interior channel 21 extending forwardly through the center of the cutting blade circular array 50 and connecting with piercing membrane 65. A shaft stem section which is not shown connects to a dye port 70 in piercing member 65 for optional delivery of marking fluid to subcutaneous areas. Dye port 70 enables operators of apparatus 10 to deliver marking

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substances to the subcutaneous excision site (see Fig. 2). Furthermore, the device comprises a plurality of electrical cutting blades and includes a connector for receiving cautery current from a power supply source (see Col. 6, Lines 23-25). It would have been obvious to one skilled in the art at the time of the invention to include a distal member in the apparatus of Gobron et al. having a smaller cross-sectional flow area than that of the lumen in order to deliver fluid to a desired target area as taught by McGuckin, Jr.

3. Claims 41-42, 59-60, and 62-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,162,209 to Gobron et al. in view of U.S. Patent No. 6,589,252 to McGuckin, Jr. in further view of U.S. Patent No. 5,947,978 to Holsinger.

In regards to claims 41-42, 59-60 and 62-68, Gobron et al. and McGuckin et al. disclose an endoscopic device but are silent with respect a nozzle member which connects to the proximal end of the end effector and is fixedly connected to a distal end of the elongated member. Holsinger teach of an analogous device having a distal member 30 fixedly secured to the actuator 18 and free end 32 for insertion into a patient having flanges 74 to secure the distal member to the elongated member (see Fig. 12). It would have been obvious to one skilled in the art at the time the invention was made to fixedly secure the distal member in the apparatus of McGuckin et al. in order to prevent objects and fluids from entering the lumen, as taught by Holsinger.

4. Claims 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,162,209 to Gobron et al. in view of U.S. Patent No. 6,589,252 to McGuckin, Jr. in further view of U.S. Patent No. 5,599,324 to McAlister et al.

In regards to claim 61, Gobron et al. and McGuikin, Jr. disclose a medical device but are silent with respect to a method of spraying a fluid that include a chromoscopic dye or a radiographic dye agent. McAlister et al. teach of an analogous device which is capable of forcing radiographic contrast agents through the lumen. It would have been obvious to one skilled in the art at the time the invention was made to use the apparatus of McGuikin, Jr et al. in order to pass such contrast agents through the lumen in order to effectively label the target site, as taught by McAlister et al.

5. Claims 4-7, 33 and 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,162,209 to Gobron et al. in view of U.S. Patent No. 5,599,324 to McAlister et al.

In regards to claims 4-7 and 33, Gobron et al. disclose a medical device but is silent with respect to a fluid supply member (syringe) for supplying fluid to the port, an interlocking member and fluid chamber sealed from a portion of the handle. McAlister et al. teach of an analogous device in which a physician can attach a syringe or other device to the second entry port 31 and force a contrast agent through the passage 35, the central volume 33 and the lumens 23 and 24 in parallel to be discharged where the lumens 23 and 24 exit the distal end 17. The seals formed between the tube 36 and the handle 12 and between the tube 36 and the catheter tube 11 around the guidewire 22 assure isolation of the guidewire lumen 22 (see Col. 5, Lines 13-22). It would have been obvious to one skilled in the art at the time of the invention to include a fluid supply assembly in the device of Gobron et al. so if it is necessary to relocate the distal tip 20, there is no need to remove the guidewire as taught by McAlister et al.

In regards to claims 51-52, Gobron et al. disclose a medical device but is silent with respect to a method of spraying a fluid that include a chromoscopic dye or a radiographic dye agent. McAlister et al. teach of an analogous device which is capable of forcing radiographic contrast agents through the lumen. It would have been obvious to one skilled in the art at the time the invention was made to use the apparatus of Gobron et al. in order to pass such contrast agents through the lumen in order to effectively label the target site, as taught by McAlister et al.

6. Claims 9-13, 16-18 and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,162,209 to Gobron et al. in view of U.S. Patent No. 5,176,688 to Narayan et al.

In regards to claims 9-13, 16-18 and 29-30, Gobron et al. disclose a medical device but is silent with respect to the distal member including a sealing member to seal the lumen wherein the distal member has a base portion and a head portion. Narayan et al. teach of an analogous device wherein the outer diameter of end cap 19 is equal to the outer diameter of sheath 21, and the cap includes a rear flange 26 which mates with the distal end portion of the sheath when the basket is fully retracted. The distal end portion of the cap is rounded to form a smooth tip 27 (see Fig. 3). It would have been obvious to one skilled in the art at the time the invention was made to include a distal member for sealing the lumen in the device of Gobron et al. so as to facilitate insertion of the extractor into the body, as taught by Narayan et al.

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7. Claims 19-27 and 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,162,209 to Gobron et al. in view of U.S. Patent No. 5,947,978 to Holsinger.

In regards to claims 19-27 and 55-57, Gobron et al. disclose a medical device but is silent with respect to the distal member connected to the proximal end of the end effector. Holsinger teach of an analogous device having a distal member 30 fixedly secured to the actuator 18 and free end 32 for insertion into a patient having flanges 74 to secure the distal member to the elongated member (see Fig. 12). It would have been obvious to one skilled in the art at the time the invention was made to include a fixedly secured distal member in the apparatus of Gobron et al. in order to prevent objects and fluids from entering the lumen, as taught by Holsinger. The apparatus of Gobron et al. would then be inherently capable of performing the recited method steps.

8. Claims 31-32 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,162,209 to Gobron et al. in view of U.S. Patent No. 5,575,694 to Hawkins et al.

In regards to claims 31-32 and 53 Gobron et al. disclose a medical device but is silent with respect to an electrical connector for receiving cautery current from a power supply source. Hawkins et al. teach of an electrical connector for attachment to a cauterizing endoscopic snare (see Col. 2, lines 57-67). It would have been obvious to one skilled in the art at the time the invention was made to include such an electrical connector in on the device of Gorbon et al. in order to provide the snare loop with an electrical current and therefore assist in surgical procedures, as taught by Hawkins et al.

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and is well-known in the art. The apparatus of Gobron et al. would then be inherently capable of performing the recited method steps.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 6,517,551 to Driskill

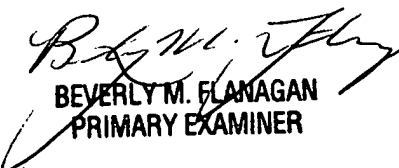
U.S. Patent No. 6,780,193 to Leslie et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kasztejna whose telephone number is (571) 272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MJK
11/17/04


BEVERLY M. FLANAGAN
PRIMARY EXAMINER